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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/746,113 12/21/00 WANG

H 3375

EXAMINER

HM12/0424

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SIEW, J

ART UNIT

PAPER NUMBER

1656

DATE MAILED:

04/24/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.

09/637,240

Applicant(s)

LEGRAIN ET AL.

Examiner

Jeffrey Siew

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 21 December 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

*Priority*

1. This application filed under former 37 CFR 1.60 lacks the necessary reference to the prior application. A statement reading "This is a continuation of Application No. 09/025151, filed 2/18/98." should be entered following the title of the invention or as the first sentence of the specification. Also, the current status of all nonprovisional parent applications referenced should be included.

*Information Disclosure Statement*

2. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

*Specification*

3. The specification is objected to because the listing of attorney docket numbers is improper. Correction is required.

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*Claim Rejections - 35 USC § 112*

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 20 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claim 20 recites synthesizing and depends on claim 1 and 6. Both claims 1 & 6 recite a step of synthesizing. It is unclear as to what step of synthesizing is being referred to.

*Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 & 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Mitsuhashi (US5,580,971 Dec. 3, 1996).

Mitsuhashi et al teach primers immobilized on solid supports which binding to fungal rRNA which are extended by reverse transcriptase producing a double stranded polynucleotide (see entire doc. esp. col. 2 lines 58-65 & Fig.2). The second primer or probe may be labeled to detect the polynucleotide.

*Claim Rejections - 35 USC § 103*

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Caskey et al (US6,153,379 Nov. 28, 2000) in view of Chetverin et al (US6,103,463 August 15, 2000).

Caskey et al teach parallel primer extension to sequence nucleic acids (see whole doc). A solid support to which is attached at defined locations one or more sets of consecutive primers differing within each set by one base (see abstract). They teach that any polynucleotide of interest including RNA is annealed to the array of oligonucleotides under hybridization conditions thereby generating annealed primers. The primers are subject to base extension under which a nucleic acid polymerase and terminating nucleotides such as ddNTPs corresponding to

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four bases. The terminating nucleotides are mutually distinguishable. The sequence of interests is then read and analyzed (see col. 2 lines 26-51 & Figure 2). They also teach analyzing polynucleotides of interest using labeled deoxynucleotides (see example 2).

Caskey et al do not explicitly teach reverse transcriptase.

Chetverin et al teach the use of reverse transcriptase in extending immobilized primers off an hybridized RNA template (see col. 64 lines 53-60)

One of ordinary skill would have been motivated to apply Chetverin et al's teaching of reverse transcriptase to Caskey et al's method in order extend of an RNA template. It was well known and commonly practiced in the art to extend of RNA templates using reverse transcriptase. It would have been prima facie obvious to apply Chetverin et al's reverse transcriptase to Caskey et al's detection method in order to extend off the hybridized RNA templates.

Moreover, it was well known and commonly practiced in the art to use thermostable reverse transcriptase enzymes in order to provide high fidelity of extension regardless of temperature fluctuations.

6. Claims 6-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Caskey et al (US6,153,379 Nov. 28, 2000) in view of Chetverin et al (US6,103,463 August 15, 2000) in further view of Chee et al (US5,861,242 Jan. 19, 1999).

The teachings and suggestions of Caskey et al and Chetverin et al are described previously.

Caskey et al do not teach synthesizing of oligonucleotides on substrate or tiling.

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Chee et al teach VSLIP synthesis of oligonucleotides in an array and tiling to sequence the sequence of genes (see whole doc esp. abstract & Figure 1). They teach a tiling strategy for analysis of HIV reverse transcriptase target gene.

One ordinary skill in the art would have been motivated to apply Chee et al's array production and design to the combined invention of Caskey et al and Chetverin et al in order to analyze multiple mutations in target sequences (see col. 5 line 29-35). It would have been prima facie obvious to apply Chee et al's array to Caskey et al's detection method in order to analyze and monitor multiple mutations in target genes such as HIV transcriptase gene.

7. Claims 3-20,26 & 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mitsuhashi (US5,580,971 Dec. 3, 1996) in view of Chee et al (US5,861,242 Jan. 19, 1999).

The teachings of Mitsuhashi et al are described previously.

Mitsuhashi et al do not teach synthesizing of oligonucleotides on substrate or tiling.

Chee et al teach VSLIP synthesis of oligonucleotides in an array and tiling to sequence the sequence of genes (see whole doc esp abstract & Figure 1). They teach a tiling strategy for analysis of HIV reverse transcriptase target gene.

One ordinary skill in the art would have been motivated to apply Chee et al's array production and design to the combined invention of Mitsuhashi et al in order to analyze multiple mutations in target sequences (see col. 5 line 29-35). It would have been prima facie obvious to apply Chee et al's array to Caskey et al's detection method in order to analyze and monitor multiple mutations in target genes such as HIV transcriptase gene.

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Moreover, it was well known and commonly practiced in the art to use thermostable reverse transcriptase enzymes in order to provide high fidelity of extension regardless of temperature fluctuations.

### CONCLUSION

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Siew whose telephone number is (703) 305-3886 and whose e-mail address is Jeffrey.Siew@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route. The examiner can best be reached on Monday through Thursday from 6:30 a.m. to 4 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703)-308-1152.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist for Technology Center 1600 whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Center numbers for Group 1600 are Voice (703) 308-3290 and Fax (703) 308-4556 or (703) 308-4242.

*Jeffrey Siew*  
4/14/01